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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,314	12/20/2001	Carlos Forray	1795/57453-CA/JPW/ADM/PL	4321

7590

07/30/2003

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EXAMINER

CRIARES, THEODORE J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/029,314

Applicant(s)

FORRAY ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4/23/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 169-197 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 169-197 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **CLAIMS 169-197 ARE PRESENTED FOR**

### **EXAMINATION**

#### ***Election/Restrictions***

Applicant's election with traverse of the compound of Example 10 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the compounds set forth in the specification share a common function and effect. This is not found persuasive because the compounds are classified in various subclasses throughout class 514 and cause an undue burden on the examiner. For example, Example 30 is classified in class 514, subclass 357 and Example 31 is classified in class 514, class 359.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined only to the extent of the elected compound.

#### **DETAILED ACTION**

Claims 169-197 are drawn to a biological pathway for the treatment of of an eating disorder or obesity. The elected compound 10 has been searched as a dihydropyrimidinone compound administered to treat eating disorders. (see page 245)

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 169-197 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds as set forth of by the compounds

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exemplified, does not reasonably provide enablement for the biological method of treatment as claimed in claims 169-197. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims encompass an astronomical number of compounds which have a specific inhibition of a biological pathway without setting forth the compounds exemplified in the specification. The skilled artisan would not be able to determine which compounds are within the scope of applicants' claims without undue experimentation.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 169-197 are rejected under 35 U.S.C. 102(a) as being anticipated by Bruce et al.(5,889,016, hereinafter referred to as Bruce).

Bruce teaches in the abstract (Formula I) and at column 4, line 66 to column 12, line 45 dihydropyrimidinone compounds can be administered to treat eating disorders. At column 12, lines 34-35 it is taught that dihydropyrimidinone compounds have utility in the treatment of "food intake disorders, such as obesity, anorexia, bulimia, and metabolic disorders;".

The biological pathway as claimed by the applicant in claims 167-197 would be inherent in the administration of the compounds taught by Bruce to treat eating disorders.

The rejection under 35 USC 102 (a) is deemed proper.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 169-197 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce et al., (supra).

As stated above Bruce teaches the administration of a dihydropyrimidinone can treat eating disorders including the treatment of eating disorders and obesity, claims 169-191 and eating disorder of claims 192-197.

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The difference between the applicants' claims and Bruce is that the dihydropyrimidinone compounds differ as the phenyl moiety is substituted with the piperazine moiety. However, the skilled artisan would be motivated to use the Bruce compounds with a reasonable expectation of success since the reference compounds are so similar to those disclosed in the specification that they would be expected to treat the claimed eating disorders.

That applicant may have determined a biological pathway by which the active ingredient gives the pharmacological effect does not alter the fact that obviously similar compounds have been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

None of the claims are allowed.

#### **SUGGESTION**

It is suggested that applicant insert into the claims compounds encompassed by example 10. Such an amendment, with a well reasoned argument, could advance the prosecution of this application.

#### **MISCELLANEOUS**

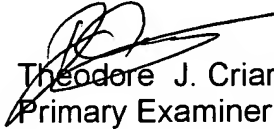
A Supplemental PTO-1449 Form has not been submitted with the papers filed September 23, 2002. It is requested that applicants furnish the required form to be acknowledged by the Examiner..

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Theodore J. Criares can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

tjc  
July 29, 2003